

REMARKS

Claims 1, 4-10, 21-29, and 31-33 are pending. Claims 3 and 8 have been cancelled without prejudice, disclaimer, or admission. Claims 1, 4-7, 24, 25-29 have been amended. Claims 31-33 have been added.

Support for amended claim 1 is found, for example, in original claims 1 and 3.

Support for amended claims 4, 5, and 6 is found, for example, in original claims 4, 5, and 6, respectively.

Support for amended claim 7 is found, for example, in original claim 7.

Support for amended claim 24 is found, for example, in original claims 24 and 3.

Support for amended claim 25 is found, for example, in original claim 25.

Support for amended claim 27 is found, for example, in original claims 27 and 3.

Support for amended claim 28 is found, for example, in original claim 28.

Support for amended claim 29 is found, for example, in original claims 29 and 3.

Support for new claims 31 and 32 is found, for example, at paragraphs 99 and 100 of the specification. Applicant points out that while new claims 31 and 32 recite amino acid sequences, they are directed to the subject matter of restricted Group I (paper no. 9), elected for prosecution in the present application. Further, as disclosed in the present specification, the nucleic acid sequence set forth at SEQ ID NO:21, which has been elected for prosecution in the present application, encodes the amino acid sequence set forth at SEQ ID NO:22, which is recited in new claims 31 and 32.

Support for new claim 33 is found, for example, in original claims 29 and 3.

Favorable consideration of the claims as amended, the newly added claims, and the remarks that follow is respectfully requested.

Objections to the Specification and Claims

The current amendment addresses each of the objections set forth in the Office Action against the present claims and present specification. In particular, by the current amendment, the specification introduces the abbreviations "CNS", "PNS", "NGF", "BDNF", "NF-L", "GAP-43", "NHRs", "NLS", and "2-ME". Further, the term "SEQ ID NOs" has been replaced by "SEQ ID NO:" throughout the specification and claims. Further, the abbreviation "Neu" has been introduced in the claims.

Claim Rejections – 35 USC § 112, Second Paragraph

Claim 1 stands rejected for use of the term “C3HC4” in the phrase “C3HC4 RING-zinc finger domain”. Applicant respectfully traverses the rejection.

The Office Action expresses that it is not clear whether the “C3HC4” term refers to a name of the domain or describes a structural feature of the domain. Applicant points out that the “C3HC4” term denominates a particular RING-zinc finger domain, and also describes a structural feature of the domain. Applicant disagrees that use of the “C3HC4” term renders claim 1 unclear, and directs the Examiner to paragraph 27 of the specification, where the meaning of the term in its present context, as stated above, is clearly set forth. Applicant further notes that claim 1 has been amended to incorporate the sequence homology limitation of original claim 3, and claim 3 has been cancelled. Applicant respectfully requests withdrawal of the rejection and allowance of amended claim 1, and claims depending therefrom (claims 4-6, and 21).

The Office Action points out that there is insufficient antecedent basis for the term “the nucleic acid” recited in claim 3. The current amendment cancels claim 3, and thereby obviates the rejection.

Claim 7 stands rejected as being indefinite for use of the phrase “polynucleotide capable of hybridization”. Without admitting the propriety of the rejection, in the interest of furthering prosecution, Applicant has replaced the phrase “polynucleotide capable of hybridization” with the phrase “polynucleotide which hybridizes” by the current amendment. Applicant requests withdrawal of the rejection and allowance of amended claim 7, as well as claims depending therefrom (claims 9 and 10).

The Office Action states that claim 8 is unclear for use of the expression “at about room temperature”. The current amendment cancels claim 8, and thereby obviates the rejection.

Claim 24 stands rejected as being indefinite for use of the term “a protein” in the phrase “a protein encoded by said nucleotide sequence”. Without admitting the propriety of the rejection, in the interest of furthering prosecution, Applicant has replaced the phrase in question with “said Neu protein encoded by said nucleotide

sequence" by the current amendment. Further with respect to claim 24, Applicant has replaced the first occurrence of the term "nucleotide sequence" with the term "polynucleotide" for clarity. Applicant points out that this amendment does not remove the antecedent basis for the later occurring phrase "said nucleotide sequence". Claim 24 has been further amended to incorporate a sequence homology limitation that finds support, for example, in original claim 3. Applicant requests withdrawal of the rejection and allowance of amended claim 24, as well as claims depending therefrom (claim 26).

Claim 25 stands rejected as being indefinite for use of the phrase "the Neu polypeptide encoding nucleotide sequence". Without admitting the propriety of the rejection, in the interest of furthering prosecution, Applicant has amended claim 25 to recite "said nucleotide sequence". Applicant requests withdrawal of the rejection and allowance of the amended claim.

Claim Rejections – 35 USC § 102

As a preliminary matter, Applicant points out that at page 4, in a discussion of the AIPA changes to 35 USC §102(e), the Office Action mistakenly states that the present application was not filed on or after November 29, 2000. Applicant notes that the present application was filed 14 March 2001.

Nakamura et al.

Claim 1 stands rejected under 35 USC §102(b) as being anticipated by *Nakamura et al.* Applicant respectfully traverses the rejection.

Claim 1 is drawn to a purified polynucleotide encoding a Neu polypeptide. With the current amendment, amended claim 1 further recites the sequence homology limitation of original claim 3, specifically, "said polynucleotide has at least 85% homology to a sequence selected from the group consisting of SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31 and 33". Support for the amendment is found, for example, in original claims 1 and 3.

Nakamura *et al.* discloses the nucleotide sequence of *h-neu*, which encodes a human homolog of the *Drosophila* neuralized gene containing a C₃HC₄-type RING zinc-finger at its C-terminus. However, Nakamura *et al.* does not disclose a polynucleotide encoding a Neu polypeptide, wherein the polynucleotide has at least 85% homology to SEQ ID NO:21, the sequence elected for examination in the present application.

As the Examiner is aware, anticipation of a claim by a reference requires that the reference teach each and every element of the subject claim. See M.P.E.P. § 2131. Thus, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See *Verdeegal Bros. v. Union Oil of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). It is imperative that the "identical invention be shown in complete detail as contained in the claim." See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Nakamura *et al.* does not disclose a polynucleotide with the sequence homology recited in amended claim 1. Accordingly, Applicant submits that Nakamura *et al.* does not disclose each and every element of claim 1 as currently amended, and thus does not anticipate the amended claim. Applicant requests withdrawal of the rejection and allowance of amended claim 1, and claims depending therefrom (claims 4-6, and 21).

Price et al.

Claim 1 stands rejected under 35 USC §102(b) as being anticipated by Price *et al.* Applicant respectfully traverses the rejection.

As discussed above, claim 1 has been amended and is currently drawn to a purified polynucleotide encoding a Neu polypeptide, wherein the polynucleotide has at least 85% homology to a sequence selected from the group consisting of SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31 and 33.

Price *et al.* discloses a cDNA encoding a *Drosophila* neuralized protein containing a C₃HC₄ zinc finger DNA-binding motif. However, Price *et al.* does not disclose a polynucleotide encoding a Neu polypeptide, wherein the polynucleotide

has at least 85% homology to SEQ ID NO:21, the sequence elected for examination in the present application.

Applicant submits that Price *et al.* does not disclose a polynucleotide having the sequence homology recited in amended claim 1. Accordingly, Applicant submits that Price *et al.* does not teach each and every element of claim 1 as currently amended, and thus does not anticipate the amended claim. Applicant requests withdrawal of the rejection and allowance of amended claim 1, and claims depending therefrom (claims 4-6 and 21).

Fleischmann et al.

Claims 7-10 stand rejected under 35 USC §102(e) as being anticipated by Fleischmann *et al.* Applicant respectfully traverses the rejections.

Fleischmann *et al.* discloses the nucleotide sequences of a variety of strains of Mycobacterium. SEQ ID NO:1 of Fleischmann *et al.* provides the nucleotide sequence of the H37Rv strain of M. tuberculosis, which is 4,411,529 nucleotides in length. Accompanying the Office Action is a sequence alignment between nucleotides 1218624-1217502 of Fleischmann *et al.* SEQ ID NO:1, and nucleotides 423-1545 of SEQ ID NO:21 of the present application. The sequence alignment reveals 43% identity between the two sequence segments, as well as two gapped regions in the alignment. The Office Action states that Fleischmann *et al.* SEQ ID NO:1 will hybridize to the present SEQ ID NO:21 under the conditions set forth in original claims 8-10 of the present application. Applicants respectfully disagree.

First, without prejudice, admission, or disclaimer, Applicant has cancelled claim 8 by the current amendment. With respect to remaining claims 7, 9, and 10, Applicant submits that examination of the sequence alignment between nucleotides 1218624-1217502 of Fleischmann *et al.* SEQ ID NO:1 and nucleotides 423-1545 of present SEQ ID NO:21, with 43% identity through these regions, clearly supports that two nucleic acids with such sequences would not hybridize to each other under the conditions recited. Applicant requests withdrawal of the rejection and allowance of claims 7, 9, and 10 as amended.

Yeh *et al.*

Claims 1, 21-24, 27, and 29 stand rejected under 35 USC §102(a) as being anticipated by Yeh *et al.* Applicant respectfully traverses the rejections.

As discussed above, claim 1 has been amended and is currently drawn to a purified polynucleotide encoding a Neu polypeptide, wherein the polynucleotide has at least 85% homology to a sequence selected from the group consisting of SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31 and 33.

Claims 21 and 22 are drawn to expression vectors comprising the polynucleotide of claim 1, while claim 23 is drawn to a host cell containing the expression vector of claim 21. Claim 24 is drawn to a method of making a Neu protein using nucleotide sequence that encodes a Neu protein. Claim 27 is drawn to a vector comprising a nucleotide sequence that encodes a Neu protein. Claim 29 is drawn to a method of constructing a transformed host cell that expresses a Neu protein using a nucleotide sequence encoding a Neu protein. Applicant points out that claims 24, 27, and 29 have been amended to recite a nucleotide sequence limitation which finds support, for example, in original claim 3. Particularly, the claims recite "said nucleotide sequence is at least 85% homologous to a sequence selected from the group consisting of SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31 and 33". Accordingly, claims 1, 21-24, 27, and 29 as amended each recite a nucleotide sequence limitation.

Yeh *et al.* reports the cloning of a 3.2kb full length *Drosophila neu* cDNA encoding a Neu protein into the vector *pUAST*. Yeh *et al.* does not disclose a polynucleotide encoding a Neu polypeptide, wherein the polynucleotide has at least 85% homology to SEQ ID NO:21, the sequence elected for examination in the present application.

Applicant submits that Yeh *et al.* does not disclose a polynucleotide having the sequence homology recited in claims 1, 24, 27 and 29 as amended. Accordingly, Applicant submits that Yeh *et al.* does not teach each and every element of any of claims 1, 24, 27, and 29 as currently amended, and thus does not anticipate the amended claims. Further, Applicant submits that Yeh *et al.* does not anticipate dependent claim 21, which depends from amended claim 1, nor

dependent claims 22 or 23, which depend from claim 21. Applicant requests withdrawal of the rejections and allowance of claims 1, 21-24, 27 and 29 as amended.

Guy et al.

Claims 24, and 26-29 stand rejected under 35 USC §102(b) as being anticipated by *Guy et al.* Applicant respectfully traverses the rejections.

As a preliminary matter, Applicant points out that the Office Action states that claims 24 and 26-29 are rejected in view of *Guy et al.*, but presents arguments for the anticipation of claims 24, 27, and 29 alone. Applicant believes the assertion that *Guy et al.* anticipates claim 28 was made in error, and respectfully requests appropriate correction and withdrawal of the rejection as applied to claim 28. Applicant further believes that the statements at page 7, paragraph 2 of the Office Action mistakenly refer to claim 24 and are intended to refer to claim 26. Applicant requests appropriate correction for the record.

As discussed above, claim 24 is drawn to a method of making a Neu protein using nucleotide sequence that encodes a Neu protein, while claims 27 and 29 are drawn to a vector comprising a nucleotide sequence that encodes a Neu protein, and a method of constructing a transformed host cell that expresses a Neu protein using a nucleotide sequence encoding a Neu protein, respectively. Further, amended claims 24, 27, and 29 each recite a nucleotide sequence limitation. Claim 26 depends from claim 24, and is drawn to a method of making a Neu protein which further comprises isolating the protein.

Guy et al. reports the use of a polynucleotide encoding an activated isoform of neu to generate transgenic mice expressing the activated neu isoform in mammary tissue. However, *Guy et al.* does not disclose a polynucleotide encoding a Neu polypeptide, wherein the polynucleotide has at least 85% homology to SEQ ID NO:21, the sequence elected for examination in the present application.

Applicant submits that *Guy et al.* does not disclose a polynucleotide having the sequence homology recited in claims 24, 27 and 29 as amended. Accordingly, Applicant submits that *Guy et al.* does not teach each and every element of claims

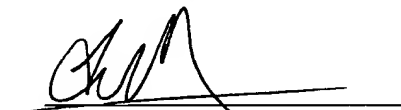
24, 27 and 29 as amended, and thus does not anticipate the amended claims. Further, Applicant submits that Guy *et al.* does not anticipate claim 26, which depends from amended claim 24, or claim 28, which depends from amended claim 27 and recites a further nucleotide sequence limitation. Applicant requests withdrawal of the rejections and allowance of claims 24 and 26-29 as amended.

CONCLUSION

Applicant submits that the application is now in condition for allowance, and early notification of such is requested. If there remain issues that the Examiner believes may be resolved by telephone, he is respectfully requested to contact the undersigned at (415) 781-1989.

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Respectfully submitted,
DORSEY & WHITNEY LLP



Todd A. Lorenz
Reg. No. 39,754

Four Embarcadero Center
Suite 3400
San Francisco, CA
94111-4187